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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 09/29/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/881,686

Applicant(s)

SEGURA ET AL.

Examiner

Lauren Q Wells

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-92 is/are pending in the application.
- 4a) Of the above claim(s) 5-7,30,44-46,49 and 91 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,8-18,20-29,31-43,47,48,50-90 and 92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

Art Unit: 1617

DETAILED ACTION

Claims 1-18, 20-92 are pending. Claims 5-7, 30, 44-46, 49 and 91 are withdrawn from consideration, as they are directed toward non-elected subject matter. The Amendment filed 7/15/03, Paper No. 19, amended claims 1-2, 9, 18, 20, 27, 41, 43, 49-50 and claims 51-92 were added.

Applicant's arguments with respect to claims 1-4, 8-18, 20-43, 47-48, 50-90 and 92 have been considered but are moot in view of the new ground(s) of rejection.

The Election of Species Requirement is maintained from Paper No. 7, filed 2/13/02. The instant Office Action withdraws the election of species requirement for gelling agents. Thus, the entire scope of gelling agents has been searched.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/15/03 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 8-18, 20-29, 31-43, 47-48, 50-90 and 92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1617

(i) The Markush language in claims 12, 27, 59, and 73 is vague and indefinite, as the language is confusing. Why is there an "or" between the first two members of the Markush group and commas between all the rest? Is Applicant denoting a special relationship between the first two members of the Markush group? Additionally, in claims 27 and 73, does "esters thereof" refer just to the fatty alcohol or to both the fatty alcohol and fatty acid.

(ii) The terms "high" and "low" in claims 14 and 61 are relative terms which render the claims indefinite. The terms "high" and "low" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Additionally, these claims are confusing. Does not the recitation of fatty alkyl ethers with high HLB values and low HLB values span all fatty alkyl ethers? Why has Applicant not just recited fatty alkyl ethers?

(iii) The percent weight recited in claim 33 is vague and indefinite, as it is confusing. What is a percent weight of "01.%"? Is it 1% or is this a typo?

(iv) Claims 34-36 and 79-81 are vague and indefinite, as they are broader than the claim from which they depend. Claims 31 and 76 recite compositions comprising a wetting agent and claims 34 and 79 recite compositions comprising a pro-penetrating and/or wetting agent. Thus, claims 34 and 79 are broader than claims 31 and 76.

(v) The term "derivative" in claims 38 and 83 (lines 3) is vague and indefinite, as the metes and bounds of this claim are unascertainable. What is a derivative of cellulose? The specification does not define this term and one of ordinary skill in the art would not be apprised of its meaning.

Art Unit: 1617

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 8-10, 15-18, 20-29, 40-43, 47-48, 50-57, 62-75, 85-90, 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lochhead et al. (EP 0 268 164) in view of the Handbook of Cosmetic Science and Technology.

The instant invention is directed toward an oil-in-water emulsion comprising a discontinuous fatty phase dispersed in a continuous aqueous phase that comprises a biologically active agent and an effective amount of an emulsifying system, wherein the active agent is non-solubilized in the emulsion and 80% has a diameter of 1-10um and 50% has a diameter of less than 5um, wherein the active can be selected from the Markush group recited in the instant independent claim, and methods of treating acne.

Lochhead et al. teach oil-in-water emulsions which contain a modified polymer which is a copolymer of an acrylic acid and a smaller amount of a long chain acrylate monomer, wherein the modified polymers function as primary emulsifiers or surfactants. The modified polymer is made by polymerizing a preponderant amount of carboxylic monomer and a lesser amount of a long chain acrylate ester, i.e. 50-99% of carboxylic monomer and 1-50% acrylate ester. Acrylic acid is taught as the preferred carboxylic monomer and higher alkyl acrylic esters, such as decyl acrylate are taught as acrylate monomers. The oil phase comprises 0.1-60% of the emulsion, the modified polymer comprises 0.05-3% of the emulsion, and the aqueous phase comprises 40-

Art Unit: 1617

99.9% of the emulsion. The emulsion has a pH of about less than 6 is disclosed. A mixture of silicone oil and mineral oil is taught as comprising the oil phase. Conventional oil-in-water emulsions preferably have a particle size of less than 10 microns and preferably 0.1-5 microns. The emulsion has an average size of 50 microns and a range of 10-100 microns.

Cyclomethicone is taught as an additive in the oil phase. Sorbitol is taught as an humectant that can be added to the emulsion in an amount of 1-10% of the emulsion. Methyl paraben, propyl paraben, and imidazolidenyl urea are taught as preservatives in the emulsion, wherein these compounds are also antibacterial agents that are insoluble in the aqueous phase of the emulsion, and comprise 0.05-0.5% of the composition. The emulsion is taught as a cleansing cream or lotion that flushes the skin and pore openings, wherein flushing skin and pore openings treats acne. The reference lacks the percent amount of the particles. See pg. 2, line 28-pg. 14, line 10.

The Handbook of Cosmetic Science and Technology teaches that a smaller emulsion particle size will lead to a greater interfacial area and, hence, a higher propensity to form a structure, and further teaches that the rate of phase separation can be reduced by reducing the dispersed phase particle size. See pages 115 and 117.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the oil-in-water emulsion of Lochhead et al. as having a diameter of 10 microns because of the expectation of achieving greater interfacial area and a propensity to form a structure and decreased phase separation, as taught by the Handbook of Cosmetic Science and Technology. Furthermore, a change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955), and it has been held that

where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

For the purposes of searching for an applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to comprising. If an applicant contends that additional steps or material in the prior art are excluded by the recitation of "consisting essentially of", applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. See MPEP 2111.03.

The claims are directed to a method of applying an oil-in-water emulsion comprising a discontinuous fatty phase dispersed in a continuous aqueous phase, an effective amount of a biologically active agent in a micronized and non-solubilized form, and an emulsifying system to the skin. Any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product. The prior art teaches application to the skin of compositions containing the same components as instantly claimed, which would inherently treat acne as instantly claimed. Applicant has not provided any evidence of record to show that the prior art compositions do not exhibit the same properties as instantly claimed.

Art Unit: 1617

Claims 11-12, 37-39, 58-59, 82-84, rejected under 35 U.S.C. 103(a) as being unpatentable over Lochhead et al. in view of the Handbook of Cosmetic Science and Technology as applied to claims 1-4, 8-10, 15-18, 20-29, 40, 41, 42, 43, 47-48, 50-57, 62-75, 85-90, 92 above, and further in view of Pisson et al. (5,882,633).

Lochhead et al. is applied as discussed above. The reference lacks a surfactant emulsifier and a thickener.

Pisson et al. teach cosmetic and/or dermatological compositions. Exemplified is an oil-in-water emulsion comprising Arlacel 165 (glyceryl and PEG-100, surfactant emulsifier) and acrylic acid/C10-C30 alkyl acrylate, wherein Arlacel 165 is a co-emulsifier for the copolymer. Guar gums and celluloses are taught as thickener additives. See Col. 10, line 3-Col. 13, line 15.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add Arlacel 165, as taught by Pisson et al., to the composition of Lochhead et al. because of the expectation of achieving an oil-in-water emulsion with less phase separation, greater solubility between the two phases, and greater stability.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the thickeners taught by Pisson et al. to the emulsions of Lochhead et al. because of the expectation of achieving a product with a thickener consistency that is easily applied as a film over the skin.

While the amount of gelling agent is not explicitly taught, it is respectfully pointed out that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Additionally, in Col. 10 of Pisson et al., the reference teaches that one of

Art Unit: 1617

ordinary skill in the art would know how much of an additive to add to the emulsion to impart the advantageous property of the additive without adversely affecting the purpose of the emulsion.

Claims 13-14 and 60-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lochhead et al. in view of the Handbook of Cosmetic Science and Technology and in view of Pisson et al. as applied to claims 1-4, 8-12, 15-18, 20-29, 37-43, 47-48, 50-59, 62-75, 82-90, 92 above, and further in view of Kaplan et al (5,916,543).

Lochhead et al. and Pisson et al. are applied as discussed above. The reference lacks a co-surfactant.

Kaplan teaches oil-in-water emulsions. Cetareth-20 (co-surfactant, fatty alkyl ether) is taught as a known oil-in-water emulsifier that enhances emulsion stability and that can be combined with other emulsifiers for enhancing emulsion stability. See Col. 2, line 15-Col. 3, line 3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate cetareth-20, as taught by Kaplan, into the composition of Lochhead et al. because of the expectation of achieving an emulsion with enhanced stability.

Claims 31-36, 76-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lochhead et al. in view of the Handbook of Cosmetic Science and Technology as applied to claims 1-4, 8-10, 15-18, 20-29, 40, 41, 42, 43, 47-48, 50-57, 62-75, 85-90, 92 above, and further in view of Kim et al. (5,980,939).

Lochhead et al. is applied as discussed above. The reference lacks wetting agents.

Kim et al. teach poloxamer 124 as a solubilizer for medicinal components and lipid

Art Unit: 1617

emulsions and as thermally stable and a gelling agent. Poloxamer 124 is exemplified as comprising approximately 4% of the composition. See Col. 6, line 27-Col. 7, line 20.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add polyoxamer 124, as taught by Kim et al., to the composition of Lochhead et al. because of the expectation of achieving an emulsion that is thermally stable and in which the active agents are well solubilized.

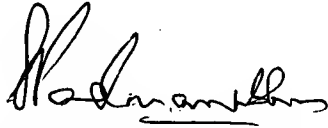
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw


SREENI PADMANABHAN
PRIMARY EXAMINER 8/29/03